

Remarks

Claims 1-24 and 31-33 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 3, 6-9, 11, 14-17, 19 and 22-24 and have cancelled claims 2, 10, 18 and 31. Support for the amendments to the claims can be found throughout the specification. No new matter has been added by these amendments. Accordingly, claims 1, 3-9, 11-17, 19-24, 32 and 33 are before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicants wish to thank Examiner Singh for the courtesy extended to the undersigned during the telephonic Examiner Interview conducted on December 16, 2008. This response and the amendments set forth herein are submitted in accordance with the substance of that interview and constitute a summary thereof. Furthermore, the claims have been amended herein in accordance with the amendments kindly suggested by the Examiner on October 27, 2008.

Claims 1-24 and 31-33 have been rejected under 35 USC §112, second paragraph. The applicants respectfully traverse this rejection to the extent that it might be applied to the claims now presented for examination.

The applicants appreciate the Examiner's careful review of the claims. The claims have been amended herein to address the issues raised by the Examiner.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph.

Claims 1-24 and 31-33 have been rejected under 35 USC §103(a) as being unpatentable over Gray *et al.* in view of Kawai *et al.*, Davis *et al.* and Siegenthaler, taken with Fritsche *et al.* and Ohashi *et al.* The applicants respectfully traverse this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicants' unique composition or its use.

A skilled artisan would have had no reason to combine the teachings of the cited references to arrive at the current invention.

The applicants claim a composition, and its use, wherein the composition has a specified amount (0.9 to 3 g per 100 ml) of milk protein hydrolysate, as well as a specified amount (2.5 to 4.5 g per 100 ml) of protein derived from fermented milk. The protein from fermented milk contains substantial quantities of whole proteins. The subject composition also contains other specified ingredients, including palatinose in an amount of 4 to 15 grams per 100 ml.

The composition claimed by the current applicants differs from the composition disclosed by the primary Gray *et al.* reference in several important aspects. First, the claimed composition has less total protein than the composition that is disclosed by Gray *et al.* The total protein content in the current applicants' composition is 3.4 to 7.5 g/100 mL of the composition. This is significantly less than the preferable amount of protein in the product disclosed by Gray *et al.* at column 6, lines 13-15, which is 94 grams/liter (*i.e.*, 9.4 g/100 mL).

Next, the claimed composition has much less protein hydrolysate than the Gray *et al.* composition. Gray *et al.* disclose at column 4, lines 5-8 that "the protein source includes approximately 80% to 85% of protein hydrolysate." Thus, the preferable amount of protein hydrolysate in the formulation of Gray *et al.* is 7.52 to 7.99 g/100 mL, which greatly exceeds the amount of milk protein hydrolysate in the nutritional composition of the present invention.

Finally, while the claimed composition has an important and significant whole protein component, Gray *et al.* repeatedly emphasize that their composition does not have any whole protein. For example, at column 2, lines 56-60 and at columns 8 and 9, Contemplative Example No. 1, Gray *et al.* emphasize the advantages of not using whole proteins.

In direct contrast to the teachings of Gray *et al.*, the applicants' composition comprises whole protein from fermented milk at 2.5-4.5 g per mL. This represents a great difference in whole protein content between the Gray *et al.* composition and the applicants' invention.

The skilled artisan would have had no motivation, or expectation of success, to combine the disparate teachings of the various cited references to arrive at the current applicants' advantageous composition.

First, with regard to the Ohashi *et al.* reference, which is relied upon in the outstanding Office Action to address the deficiencies of the Gray *et al.* reference with respect to the protein content of the composition, there is no reason why the skilled artisan would even consider combining the teachings of these two references. Specifically, Ohashi *et al.* do not disclose or suggest the use of their elemental diet for patients under high levels of invasive stress. Accordingly, the skilled artisan would have had no motivation to combine these teachings in the first place.

Furthermore, even if these references were somehow combined, one would not arrive at the current invention. Ohashi *et al.* describe a low protein diet of amino acids, carbohydrates, fats, vitamins, and minerals. Gray *et al.* explicitly disclose at column 2, lines 47-50 that “an advantage of the present invention is to provide a composition having a high protein content,” (emphasis added) and at column 3, lines 57-59 Gray *et al.* state that “due to increased metabolic activity, such patients require high protein intake to reduce negative nitrogen balance and support wound repair.”

The teachings of Ohashi *et al.* are opposite to the purpose of the enteral formulation of Gray *et al.*, and thus, a skilled artisan would have had no motivation to combine the two teachings to arrive at the current invention.

The Office Action indicates that it would have been obvious to a person of ordinary skill in the art to modify the composition of Gray *et al.*, in view of Siegenthaler, such that it includes a protein from fermented milk, such as quark. The applicants respectfully disagree.

The fermented milk of Siegenthaler contains significant amounts of whole proteins; therefore, one skilled in art would not have been motivated to combine the teachings of Siegenthaler with that of Gray *et al.* Thus, the applicants respectfully submit that one of ordinary skill in the art would have had no reason to combine fermented milk products into the enteral formulation of Gray *et al.*

The remarks at page 10 of the outstanding Office Action appear to discount the reasons not to combine these references. It thus appears that hindsight, using the benefit of the applicants’ disclosure, has been a factor in making this combination of references. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969).

Davis *et al.* primarily aim at suppressing angiotensin-converting enzyme (ACE), and providing a composition effective therefor. Nowhere in the disclosure of Davis *et al.* is there a suggestion of applying enzymatically hydrolyzed whey proteins to patients under high level of invasive stress. The purpose of the composition of Davis *et al.* containing enzymatically hydrolyzed whey proteins, is completely different from the purpose of the enteral formulation of Gray *et al.*, the former being for suppressing ACE activity and the later being for providing nutritional support to a trauma, burn or post-surgery patient. The applicants respectfully submit that it would not have been obvious to a skilled artisan to modify the composition of Gray *et al.* such that it includes a protein hydrolysate obtained by enzymatic hydrolysis of a WPI, nor would there have been a reasonable expectation of success.

The Office Action also indicates that it would have been obvious to a person of ordinary skill in the art to modify the composition of Gray *et al.* such that it includes a non-calorigenic carbohydrate such as palatinose, because Kawai *et al.* disclose a non-calorigenic substitute for carbohydrate source.

The applicants would like to bring the Examiner's attention to column 2, lines 51-55 of Gray *et al.* which discloses that "an advantage of the present invention is to provide a composition that has reduced water and carbohydrate content, reducing the risk of diarrhea due to carbohydrate intolerance, hyperglycemia..." (emphasis added).

As per MPEP 2143.01, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

A person with ordinary skill in the art would not have had motivation to use palatinose as discussed by Kawai *et al.* in the reduced carbohydrate composition of Gray *et al.* Please note that the claims have been amended herein to recite that the composition of the subject invention has 4 to 15 grams per 100 ml of palatinose.

As in the case of the combination of the Siegenthaler reference with Gray *et al.*, the analysis at pages 10 and 11 of the outstanding Office Action with regard to the Davis *et al.* reference and the Kawai *et al.* reference appears to rely heavily on hindsight to find a motivation to combine the references, while discounting the reasons why the references would not be combined by a skilled artisan. As noted above, hindsight cannot be used in establishing a basis to combine references. This was specifically recognized by the CCPA in *In re Spornoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The applicants also take issue with the Examiner's interpretation of the term "protein derived from fermented milk" as set forth at page 9 of the outstanding Office Action.

In any event, in order to expedite prosecution, the applicants have adopted herein the claim language kindly proposed by the Examiner in his Communication dated October 27, 2008.

For the reasons explained above, one of ordinary skill in the art would not combine Gray *et al.* with the cited secondary references to arrive at the applicants' specific advantageous composition. Furthermore, the applicants have adopted the claim language previously indicated to be allowable. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §103(a).

Claims 1-24 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 37 and 38 of copending Application No. 10/487,237. Please note that the applicant is submitting herewith a Terminal Disclaimer with respect to the '237 application.

The applicants' submission of a Terminal Disclaimer has been done to expedite prosecution and should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the double patenting rejection set forth in the outstanding Office Action. The applicants respectfully request reconsideration and withdrawal of this rejection in view of the submission of the Terminal Disclaimer.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik
Patent Attorney
Registration No. 31,794
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRS/la

Attachments: Terminal Disclaimer